Summary of Adverse Safety and Effectiveness Information

A literature search was performed by Dideco, and utilized Medline, Biological abstracts, (BIO), Engineering Index (EIX), Engineering Meetings (EIM) databases. A bibliography of the citations obtained is enclosed. The search revealed no adverse information on Venous/Cardiotomy Reservoir devices (VCR): they have been recognised for their importance in the extra corporeal circuit from early on in the history of cardiopulmonary bypass surgery.[1, 5, 22, 29] These filters are used to remove solid particles from the extra corporeal circuit and gaseous micro-emboli produced by the circuit. [1, 2, 3, 4, 5, 6, 18, 20, 22, 30]

There has been research conducted however on the effects of cardiotomy suction during cardiac surgery in relation to cellular host defences, and the role of cardiotomy suction in causing erythrocyte damage during cardiac surgery.

1) The concerns about airborne contamination during reinfusion of shed mediastinal blood cannot be substantiated by clinical evidences, [19, 24] in an animal study, Van Oeveren, et al., found that when airborne contamination is present in the wound area and cardiotomy suction is employed, the type of oxygenator used in the circuit may affect the host defence. They concluded that the use of a membrane oxygenator is helpful to maintain the host defences [7, 8, 33]

2) In an in vitro study of the role of cardiotomy suction in causing erythrocyte damage during cardiac surgery, Knight, et. al., found that the suctioning of air caused plasma hemoglobin levels to increase by a factor of two to five. A cardiotomy reservoir was effective in reducing hemolysis only in cases where excessive foaming was present. [4, 30] Complement activation and hemolysis remain an area of concern in VCR's, although a better choice in design and materials led to reduced blood trauma. [16, 22, 25, 26, 28, 31, 32]
The greatest source of hemolysis in procedures using VCR's has been frequently found to be drugs or the blood to air interface via the suctioned blood, not the cardiotomy itself. [23, 25, 29, 30, 32, 33]

3) The use of reservoirs incorporating a filter helps in removing aggregates or cellular debris from stored blood [9, 19, 24, 27, 30, 34] even if such blood is defibrinogenated and does not induce coagulopathy [6, 19, 24] further research into more hemocompatible materials for cardiopulmonary bypass circuits are required.[16, 25]

4) Excessive amount of negative pressure in the reservoir contribute to hemolysis and may induce the reservoir implosion or paradoxic obstruction.[13] The use of a relief valve may be successful to prevent such hazard. [23]

5) Especially for the pediatric population, the reduction in priming volume is desirable in order to minimize the use of donor blood, to avoid the hemodilution and to reduce the synthetic surface exposure. [10, 11, 12, 13, 14, 15, 17, 30, 34] Small hold-up volumes and little breakthrough time are beneficial in case of small volumes or an excess of suctioned blood as in paediatric practice. [17, 25, 26, 30, 34] The larger microfiltration pore size has also been mentioned in inducing more blood volume sequestration. [21, 30]

6) Air embolism is still a potential complication in hard-shell cardiotomy reservoirs. [23, 29, 30] Every effort should be directed to eliminate this hazard by using electronic air detectors and micropore filters between cardiotomy return and the oxygenator.[29, 30, 31]

7) Human trials[15, 17, 23, 24, 25, 26, 35] have been performed on Dideco Venomidicard-Midicard, and no concerns about the device's safety or effectiveness issues have been raised.

8) Although not specifically addressed in the literature, the largest source of customer complaints, as determined by MDR reports, for all types of cardiotomies is cardiotomy leaks. The second most frequently cited customer complaint is the filtering media occlusion.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Mr. Barry Sall
Senior Regulatory Consultant
Parexel International Corp.
195 West Street
Waltham, MA 02451-1163

Re: K001602
Trade Name: Dideco D920 Lilliput 1 Twin reservoir Ph.I.S.I.O
Regulatory Class: II (two)
Product Code: DTN
Dated: May 23, 2000
Received: May 24, 2000

Dear Mr. Sall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Brian E. Hanrahan for

James E. Dillard III
Director
Divison of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001602

Device Name: Dideco D920 Lilliput 1 Twin reservoir Ph.I.S.I.O.

Indications For Use:

The Dideco D920 is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for whom a low circuit priming volume is required. The venous reservoir with cardiotomy filter is intended for use as a storage reservoir (gravity or vacuum-assisted) for venous return blood and as a filtered reservoir for cardiac suction during ECC. The cardiotomy reservoir has the same intended use as the afore mentioned venous reservoir, as a filtered reservoir for cardiac suction blood in a bypass extracorporeal circuit, but does not have a venous return. Following intraoperative use, the reservoirs are used for the collection and autotransfusion of shed blood.
The D920 Lilliput 1 Twin reservoir Ph.I.S.I.O. should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001602

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescritpion Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Otional format 1-2-96)